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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,510	03/24/2004	Tao Lu Lowe	059516-0058	3378
7590 10/16/2008 MCDERMOTT, WILL & EMERY 600 13th Street, N.W. Washington, DC 20005-3096				
EXAMINER FUBARA, BLESSING M				
ART UNIT 1618		PAPER NUMBER		
MAIL DATE 10/16/2008		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/807,510

Applicant(s)

LOWE ET AL.

Examiner

BLESSING M. FUBARA

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 10-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 9 and 16-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The examiner acknowledges receipt of amendment and remarks filed 7/14/08. Claims 3-5 are amended. Claims 1-24 are pending. Claims 7 and 10-15 are withdrawn from consideration.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims , 16 and 20-21 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

The boundaries of elastin-like polypeptides in claim 3 are not described.

The meets and bounds of substance in claim 16 are not described. While elastin is known, it is unclear what all variations can be made to be within the scope of "like" when varying elastin.

Response to Arguments

3. Applicant's arguments filed 7/14/08 have been fully considered but they are not persuasive.
4. Applicant says that the amendment to the claims deleting derivatives from claims 3-5 overcomes the rejections. But claim 3 continues to recite elastin-like polypeptides and it is

unclear what the boundaries are for elastin like. Also the boundaries of "substance" in claim 16 are not described and it is not known. Applicant has not addressed these.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 4-6, 8, 9, 16-21 and 23 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hennink et al. (WO 98/00170) for reasons of record and reiterated herein below.

7. Hennink describes a hydrolysable hydrogels for controlled release of drugs such as protein drugs cytokine interleukin (abstract; page 1, lines 22-33; page 12, lines 14-31) with the hydrogel composition for the delivery of the protein drug meeting claims 16-19. The administration of the composition comprising the hydrolysable hydrogel polymer and the protein drugs to human (page 2, lines 4-19; page 3, line 30; page 5, lines 28 and 29; page 6, lines 7 and 8; and page 13, lines 9-19) meets the limitations of claims 20 and 21. The drugs in Henning are loaded into the hydrogel in an aqueous solution (page 4, lines 15-23; page 6, line 2) meeting claim 23. The hydrolysable polymer of Hennink has polyglycolic acid and or polylactic acid spacers between methacrylate type polymer and dextran (page 7, lines 24-36; pages 8; Examples 2, 3 and 4); the lactide or glycolide meets claim 4; the dextran meets claim 5 and the triblock polymer meets the generic polymer of claim 1 having the biodegradable segment, lactic acid and dextran and the smart segment, HEMA. Furthermore, the hydrogel composition is prepared in

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the form of microspheres (page 3, line 7; page 10, lines 26-34; page 12, line 7; page 13, line 21) meeting claim 8. Claims 2 and 9 recite the properties of the polymer and the polymer composition so that the polymer and polymer composition of Hennink meet those claims.

Response to Arguments

8. Applicant's arguments filed 7/14/08 have been fully considered but they are not persuasive.

9. Applicant argues that Hennink fails to disclose all the elements of claim 1 since according to the applicant, Hennink's polymer does not have a smart segment and that HEMA is not a smart polymer as would be recognized by the ordinary skilled artisan. The examiner disagrees. As per applicant, citing paragraph 28 of the specification: "the smart segment is responsive to an external stimulus, such as a chemical, biological, or physical stimulus, and sharply changes at least one of its physical properties in response to the stimulus. For example, bio-responsive polymers respond to physical, chemical, or biological stimuli, such as temperature, pH, ionic strength, magnetic field, electrical field, pressure, light, enzyme, receptor, glucose, etc. by altering their swelling behavior, permeability or mechanical strength." In the same way, HEMA is known in the art to as bio-responsive material as evidenced by column 8, lines 35-44 of US 6,488,872. Therefore, Hennink teaches all the limitations of the claims and the rejection is properly 102(b).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 3, 22 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hennink et al. (WO 98/00170) in view of Merchant (US 20020068087) for reasons of record and reiterated herein below.

Hennink is discussed above as anticipating claims 1 and 2. Regarding claims 22 and 24, the artisan would have good reason to administer the composition having the appropriate concentration of the drug with the expectation that the delivery of the desired amounts of the drug would be released for effect the desired result. Hennink's polymer does not have the polymer of claim 3 as one of the polymers. However, hydrogel compositions containing poly N-isopropylacrylamide as a temperature sensitive polymer are known to be used in the delivery of protein drugs such as interleukins (paragraphs [0014], [0087], [0088] and [0099]. Therefore,

taking the general teaching of the references, one having ordinary skill in the art would have reasonable expectation of success using poly N-isopropylacrylamide in place of HEMA would produce a polymer that would be effective to deliver interleukin.

Response to Arguments

13. Applicant's arguments filed 7/14/08 have been fully considered but they are not persuasive.

14. Applicant argues that Hennink does not disclose polymeric material containing a smart segment and that the rejection cannot be sustained by mere conclusory statements without articulated reasoning that has some rational underpinning to support the legal conclusion of obviousness. Applicant further argues that Merchant does not cure the deficiencies of Hennink noting that Merchant mentions poly N-isopropylacrylamide in the background.

15. The examiner disagrees. It was shown above that Hennink discloses a polymer that has a smart segment since HEMA is bio-responsive as evidenced by column 8, lines 35-44 of US 6,488,872, so that the polymer of Hennink has a smart segment. Hennink's hydrogel composition is a controlled release composition that controllably releases interleukin, a protein drug. Merchant is relied upon for teaching that composition containing N-isopropylacrylamide, a responsive polymer, is known to be used in the delivery of interleukin protein drug. There is thus an expectation of success that using the polyisopropylacrylamide in place of the HEMA would reasonably lead to a polymer that would successfully effectively deliver interleukin. Thus Merchant cures the deficiency of Hennink in failing to have the poly N-isopropylacrylamide as one of the segments in the polymer. This is the same reasoning provided in the office action of 4/16/2008 --- the reasons were articulated.

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618